UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,753	08/31/2000	Sonti Venkata Ramakrishna	U 012932-5	3517

140 7590 02/28/2006

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER	
JUNG, UNSU	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/652,753	RAMAKRISHNA ET AL.	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20 and 22-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 22-36* is/are rejected.

7)☒ Claim(s) *22-36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 20 and 22-36 are pending.

Claim Objections

2. Claim 29 is objected to because of the following informalities: the abbreviated form of the term "mixed liquor suspended solids", MLSS, should be used in claim 29 as the term "mixed liquor suspended solids" was abbreviated in claim 22. Appropriate correction is required.

3. Claims 22-32, 34, and 36 are objected to because of the following informalities: a comma is needed preceding the word "wherein" in line 1. Appropriate correction is required.

4. Claims 33 and 35 are objected to because of the following informalities: a comma is needed preceding the word "further" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 23, 24, 25, 28, 32, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In claim 23, the term "stable biosensing granules" in lines 5-6 is vague and indefinite. It is unclear whether or not the term "stable biosensing granules" is referring to "stable biosensing granules" in line 13 of claim 20.

8. Regarding claim 24, the parentheses in line 2 renders the claim indefinite because it is unclear whether the limitation(s) within the parentheses are part of the claimed invention.

9. The term "about" in claim 25 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The parameter of "pH" has been rendered indefinite by the use of the term "about" in line 2.

10. The term "about" in claim 28 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

not be reasonably apprised of the scope of the invention. The parameter of "temperature" has been rendered indefinite by the use of the term "about" in line 2.

11. In claim 29, the term "mixed liquor suspended solids (MLSS)" in lines 2-3 is vague and indefinite. It is unclear whether or not the term "mixed liquor suspended solids (MLSS)" is referring to "mixed liquor suspended solids (MLSS)" in lines 8-9 of claim 22.

12. In claim 32, the term "immobilized biosensing granules" in line 2 is vague and indefinite. It is unclear whether or not the term "immobilized biosensing granules" is referring to "immobilized biosensing granules" in line 11 of claim 20.

13. Claim 34 recites the limitation "the aqueous liquid" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Rejections Withdrawn

14. Applicant's arguments, see p6, filed on September 29, 2005, with respect to the obvious type double patenting rejection have been fully considered and are persuasive. The obvious type double patenting rejection of claims 20, 22-23, 25-28, 30-34, and 36 as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan has been withdrawn.

15. Applicant's arguments, see p6, filed on September 29, 2005, with respect to the obvious type double patenting rejection have been fully considered and are persuasive. The obvious type double patenting rejection of claim 24 as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan, and further in view of Moreton et al. and Shimizu et al. has been withdrawn.

16. Applicant's arguments, see p6, filed on September 29, 2005, with respect to the obvious type double patenting rejection have been fully considered and are persuasive. The obvious type double patenting rejection of claim 29 as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan, and further in view of Husain et al.

17. Applicant's arguments, see p6, filed on September 29, 2005, with respect to the obvious type double patenting rejection have been fully considered and are persuasive. The obvious type double patenting rejection of claim 35 as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan, and further in view of Kikuta et al.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 20, 22-23, 25-28, 30-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (U.S. Patent No. 6,420,146, Filed Mar. 30, 2000) in view of Yuan (U.S. Patent No. 6,153,416, Filed Jan. 20, 1999).

Ramakrishna et al. teach a process for the preparation of stable yeast crystals. According to the invention, yeast is grown by inoculation in media that was sterilized at 12 1 degrees Celsius after the pH had been adjusted to 6.8-7.2 using 1 N sodium chloride or 1 N hydrochloric acid. This was then incubated on a shaker at 26-30 degrees Celsius for about 24 hours with aeration. The yeast was then separated by centrifugation at 5,000-15,000 rpm for 10 minutes at 24-32 degrees Celsius. A yeast slurry was then prepared by mixing the yeast 0.5-10% with 0.5-3% natural polymer solution. The immobilized yeast beads were then prepared by adding this solution dropwise into a curing solution of 0.05-0.3 M calcium chloride solution. The beads were kept in this solution overnight at a temperature of 4 degrees Celsius. The immobilized yeast beads were then separated by decanting the solution and washed with distilled water several times. The beads were then dehydrated at a temperature of 24-36 degrees Celsius fir 2-20 hours to obtain stable yeast crystals having a moisture content of 5-30%. These crystals were activated by incubation in 5-8% molasses solution for 2-48 hours at 24-32 degrees Celsius. The yeast crystals were then separated by draining this aqueous solution (Co1. 4, lines 8-53). Sodium alginate 2% was generally used in preparing the yeast slurry (Col. 4, lines 64). However, the reference does not teach selecting a culture from activated sludge.

Yuan teaches the immobilization of microbial cells in polymeric beads. The process of the reference can be used effectively to immobilize yeast, as well as activated sludge microorganisms and waste water treatment microorganisms (Col. 2, line 63 - Col. 3, line 5).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the microbial consortia obtained from wastewater treatment plants as taught by Yuan with the method of Ramakrishna et al. because Yuan teaches that both yeast and waste water microorganisms can be used for immobilization onto beads. Therefore, one could have substituted wastewater microorganisms for the yeast in Ramakrishna et al. with a reasonable expectation of success. It would also have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the specific aeration of 5 ml/minute. The selection of this parameter merely represents an optimization of the assay protocol and does not patentably distinguish the claimed invention over the prior art of record. One of skill in the art would easily be capable of selecting an appropriate aeration rate that promotes yeast growth. Further, the reference discloses the use of 1 N solution to adjust pH, as opposed to 0.1 N as claimed. However, it would have been obvious to use 0.1 N solutions with the invention of the reference because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In this case, the use of a less concentrated solution allows for the concentration of the media to be adjusted at a more gradual rate than if using a more concentrated solution, with the selection of the preferred concentration well within the skill of those in the art.

22. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (U.S. Patent No. 6,420,146, Filed Mar. 30, 2000) in view of Yuan

(U.S. Patent No. 6,153,416, Filed Jan. 20, 1999) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Moreton et al. (U.S. Patent No. 4,778,630, Oct. 18, 1998) and Shimizu et al. (U.S. Patent No. 4,355,111, Oct. 19, 1982).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the references do not teach the specific components of the growth media or glucose as the activation solution.

Moreton et al. teach the use of a growth medium comprising potassium dihydrogen orthophosphate, disodium hydrogen orthophosphate, yeast extract, glucose, ammonium chloride, and urea (Col. 4). The reference does not teach sodium bicarbonate or tryptone in media.

Shimizu et al. teach a growth medium comprising sodium bicarbonate and tryptone (claims).

It would have been *prima facie* obvious to one of ordinary skill in the art to use the growth media of Moreton et al. with the modified method of Ramakrishna et al. and Yuan because the selection of the growth media merely represents an optimization of the assay protocol that does not patentably distinguish the claimed invention over the prior art. One of skilled in the art would easily be able to select an appropriate growth media for culturing various microorganisms. In addition, although Moreton et al. does not specifically teach tryptone, it allows for the use of other carbon sources, of which tryptone is an example, and Shimizu et al. teach the use of tryptone in media for the growth of microorganisms. In addition, Shimizu teaches sodium bicarbonate in media, which one of skill in the art could have easily substituted for the salts in the media of

Moreton with a reasonable expectation of success, as calcium in calcium chloride and sodium in sodium bicarbonate are metals belonging to adjacent periods in the periodic table with similar properties. Furthermore, it would have been obvious to substitute dipotassium hydrogen orthophosphate for the disodium hydrogen orthophosphate in Moreton et al. because sodium and potassium belong to the same period in the periodic table, and one of skilled in the art could reasonable expect them to have very similar properties.

23. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (U.S. Patent No. 6,420,146, Filed Mar. 30, 2000) in view of Yuan (U.S. Patent No. 6,153,416, Filed Jan. 20, 1999) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Husain et al. (U.S. Patent No. 6,361,695, Filed Oct. 2, 1999).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the references do not teach the termination of growth at an MLSS of 14,500-15,500 mg/liter.

Husain et al. teach a wastewater treatment system wherein when the MLSS reaches levels of 15 g/1 (15,000 mg/liter), some of the mixed liquor is removed from the bioreactor. The MLSS levels must be below this level for effective effluent treatment.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the MLSS levels of Husain et al. with the modified method of Ramakrishna et al. and Yuan because after an MLSS of 15,000 mg/liter has been

reached, optimal conditions for effluent treatment and growth of microbes no longer exist.

24. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (U.S. Patent No. 6,420,146, Filed Mar. 30, 2000) in view of Yuan (U.S. Patent No. 6,153,416, Filed Jan. 20, 1999) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Kikuta et al. (US Pat. 5,990,191, Published June 5, 1997).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the references do not teach glucose as the activation solution.

Kikuta et al. teach a glucose solution for the activation of carriers with microorganisms immobilized thereon (Col. 10).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute glucose as the activation solution as taught by Kikuta et al. for molasses as taught by Ramakrishna et al. because both are very well known carbon sources, and Kikuta et al. teach that glucose can be used for activation, which would provide one of skill in the art a reasonable expectation of success in making the substitution.

Response to Arguments

25. Applicant did not address the rejections made under 35 U.S.C. 103(a) in the Office Action filed on February 8, 2005. Therefore, the rejections under 35 U.S.C. 103(a) in the Office Action filed on February 8, 2005 have been maintained.

Conclusion

26. No claim is allowed.

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Unsu Jung, Ph.D.
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/17/06